8-23-99

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DATA EVALUATION RECORD

PROHEXADIONE CALCIUM
(BAS 125 08 W)

Study Type: §81-5; Primary Dermal Irritation

Work Assignment No. 1-02-25FF (MRID 44457740)

Prepared for
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U.S. Environmental Protection Agency
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Date: 6/18/99

Disclaimer

This Data Evaluation Record may have been altered by the Health Effects Division subsequent to signing by Dynamac Corporation personnel.

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Prohexadione Calcium (BAS 125 08 W) Primary Dermal Irritation Study (81-5)

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Registration Action Branch 2 (7509C)

For AK Mcgrath 8/23/99

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Toxicology Branch I (7509C)

for SD Mcgrath 8/23/99

DATA EVALUATION RECORD

STUDY TYPE: Primary Dermal Irritation - Rabbit
OPPTS Number: 870.2500 OPP Guideline Number: §81-5

DP BARCODE: D246707 SUBMISSION CODE: S543930
P.C. CODE: 112600 TOX. CHEM. NO.: None

TEST MATERIAL (PURITY): Prohexadione calcium (74.9% purity)

SYNONYMS: BAS 125 08 W; calcium salt of 3-oxido-4-propionyl-5-oxo-3-cyclohexene-carboxylate

CITATION: Poelloth, C. (1996) Study on the acute dermal irritation/corrosion of BAS 125 08 W in the rabbit. BASF Aktiengesellschaft, Ludwigshafen/Rhine, Federal Republic of Germany. Laboratory Project Number 14H0242/952069. January 31, 1996. MRID 44457740. Unpublished.

SPONSOR: BASF Corporation, P.O. Box 13528, Research Triangle Park, NC.

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 44457740), six young adult New Zealand White rabbits were dermally exposed to 0.5 g of prohexadione calcium (74.9% purity) for 4 hours; the test substance was moistened with distilled water and applied to a single intact 6.25-cm^2 site/animal. Animals were observed for dermal irritation for up to 15 days following patch removal.

One hour following patch removal, moderate/severe to severe erythema was observed at 6/6 sites, very slight edema was observed at 3/6 sites, and "mechanical skin lesions due to adhesive test substance" was observed at 6/6 sites. By 72 hours, very slight to well-defined erythema (mean score of 1.0) persisted at 5/6 sites and mechanical skin lesions persisted at 4/6 sites. All irritation subsided by day 15. In this study, **prohexadione calcium is a mild to moderate dermal irritant and a significant dermal adhesive**, and is best classified as **TOXICITY CATEGORY III** for primary dermal irritation based on the degree of effects observed at 72 hours.

This study is classified **acceptable (§81-5)** and satisfies guideline requirements for a primary dermal irritation study in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: Prohexadione calcium (BAS 125 08 W)
   Description: Light brown granules
   Lot/Batch #: AF 284-79
   Purity: 74.9%
   CAS #: 127277-53-6

2. Vehicle and/or positive control: Distilled water, unspecified volume/application

3. Test animals: Species: Rabbit
   Strain: New Zealand White (SPF)
   Age: Young adult
   Weight: 3.66-3.99 kg (combined sexes)
   Source: Dr. K. Thomae GMBH, Biberach, Federal Republic of Germany
   Acclimation period: ≥1 Week
   Diet: Kliba-Labordiaet 341, Klingentalmuehle AG Kaiseraugst, Switzerland, approximately 130 g/animal/day
   Water: Tap water, 250 mL/animal/day
   Housing: One animal/cage in stainless steel wire mesh cages
   Environmental conditions:
   Temperature: 20-24 °C
   Humidity: 30-70%
   Air changes: Not specified
   Photoperiod: 12-hour light/dark cycle

B. STUDY DESIGN and METHODS:

1. In-life dates: July 24 - August 8, 1995

2. Animal assignment and treatment: Fur from the dorsal trunk areas of six young adult New Zealand White rabbits (four male and two female) was clipped at least 24 hours prior to dermal administration with 0.5 g of prohexadione calcium. The test substance was moistened with distilled water and applied to a single intact application site/animal

using a 6.25-cm^2 test patch. The patches were secured with Fixomull stretch adhesive fleece. Following a 4-hour exposure period, the coverings were removed, and the test sites were gently wiped with polyethylene glycol/water. The rabbits were observed for dermal irritation 1, 24, 48, and 72 hours and 8 and 15 days following patch removal. Erythema and edema were scored separately using the table outlined in OECD Guideline 404 (same as the Draize scale). Animals were also observed for clinical signs of toxicity and/or mortality once daily during the 15-day study.

II. RESULTS AND DISCUSSION:

A. Clinical observations: One hour following patch removal, moderate/severe to severe erythema (scores of 2-3) was observed at 6/6 sites and very slight edema (score of 1) was observed at 3/6 sites. In addition, the study author reported that all sites exhibited "mechanical skin lesions due to adhesive test substance" [page 16].[1] Edema subsided from all sites by 24 hours. By 72 hours, very slight to well-defined erythema (scores of 1-2; mean of 1.0) persisted at 5/6 sites and mechanical skin lesions persisted at 4/6 sites. Erythema and mechanical skin lesions subsided from all test sites by 15 and 8 days, respectively. In this study, prohexadione calcium is a mild to moderate dermal irritant and is a significant dermal adhesive.

B. Deficiencies: There were no deficiencies that affected the results of this study. It should be noted that in a concurrently-submitted primary dermal irritation study (MRID 44457746) conducted with prohexadione calcium technical (93.3% purity), no dermal irritation was observed during the 72-hour observation period.

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[1]The reviewer interpreted this statement as lesions caused upon removal of the strongly adhesive test material; this observation was included in the overall assessment of its irritation properties.